

REMARKS

I. Status of the Claims

Claims 2-9 are pending.

II. Evidence of Unexpected Results Are Found In Summaries of Clinical Trials in the Investigators' Brochures Sent to the FDA

As the Examiner specified in the Interview Summary mailed May 8, 2006, the remaining rejection is for obviousness over the inventor's own work.

A Declaration under 37 CFR § 1.132 is submitted herein by the inventor, Joel E Bernstein, M.D. His Declaration relates to unusual and unexpected results of clinical trials conducted as part of regulatory submissions of the FDA. The unusual and unexpected results are that in contrast to the palliative effects of most pain relievers, which cease upon cessation of administration, the protocol for civamide cream and nasal spray resulted, in many cases, in effects lasting beyond cessation of drug administration. Exhibits B and C summarize results of the clinical trials from the (Investigators' Brochure)

These effects cannot be discounted on the basis of "inherency." To satisfy the legal criterion of inherency, the characteristic must have been able to be recognized and used by those of skill in the art. When anticipation is based on inherency of limitations not expressly disclosed in the assertedly anticipating reference, it must be shown the undisclosed information was known to be present in the subject matter of the reference. *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. and Research*, 2002 U.S. App LEXIS 18007, *15, (Fed. Cir. 2002); *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749-50 (Fed. Cir. 1991). An inherent limitation is one that is necessarily present; invalidation based on inherency is not established by "probabilities or possibilities." 2002 U.S. App LEXIS at *15; *Scaltech, Inc. v. Retec/Tetra, LLC.*, 178 F.3d 1378, 1384, 51 USPQ2d 1055, 1059 (Fed. Cir. 1999). Inherency cannot be based on the knowledge of the inventor; facts asserted to be inherent in the prior art must be shown by evidence from the prior art. *In re Debizak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). The purpose of the rule of inherency is to accommodate common knowledge, knowledge that judges might not know but that would be known to practitioners in the field. 2002 U.S. App LEXIS 18007 at *18; *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1365, 51 USPQ2d 1001, 1009 (Fed. Cir. 1999). "If the [prior art] limitation is inherently disclosed... it must be necessarily present and a person of ordinary skill in the art would recognize its

presence.” *Crown Operations Int’l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1377; *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed Cir. 1999). To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Finnigan Corporation, v. U.S. Int’l Trade Comm’n*, 180 F.3d 1354 (Fed. Cir. 1999).

What is taught in Bernstein ’060 is that civamide “is much more potent as a depleter of neuropeptides from sensory nerves than is capsaicin” (the compound to be replace) and that “such neuropeptide depletion” was achieved “without producing the extreme degree of burning or stinging produced by capsaisin.” Although the civamide is an improvement, it is still produced some local irritation in the form of burning, stinging and vasodilation. There was no teaching or suggestion in ’060 that pain relief could persist after cessation of treatment.

Without the teachings of the present invention, those of skill would not have appreciated the prolonged effect of treatment including intermittent treatment and would have civamide continuously, or at least, longer than necessary, increasing duration of unpleasant side effects.


III. Other

Applicant appreciates the Examiner’s suggestions and requests allowance of pending claims.

A Petition for a three month extension of time until June 28, 2006 is filed concurrently with the required fee.

No other fees are believed to be owed in connection with the submission of these amendments. However, please charge any fees that might be due in connection with this paper to the Account of Barnes & Thornburg LLP, Deposit Account 12-0913 with reference to file 41957/102740.

Respectfully submitted,
BARNES & THORNBURG LLP


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